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Anti-kickback Statute and Physician Self-Referral Laws (Stark Laws) By Kevin E. Vorenkamp, M.D., FASA

There can be confusion understanding the differences between the Anti-kickback Statute and the Physician Self-Referral Laws, or Stark laws. Although both are aimed at limiting cost and corruption of medical decision making, there are important differences between the two.

The federal **Anti-Kickback Statute** (AKS) (See <u>42 U.S.C.</u> § <u>1320a-7b.</u>) is a **criminal statute** that prohibits the exchange (or offer to exchange), of anything of value, in an effort to induce (or reward) the referral of business reimbursable by federal health care programs. Examples of prohibited kickbacks include receiving financial incentives for referrals, free or very low rent for office space, or excessive compensation for medical directorships. Other kickbacks include waving copayments, either routinely or on a selective case-by-case basis. The Centers for Medicare and Medicaid Services (CMS) claims that kickbacks have led to overutilization and increased costs of healthcare services, corruption of medical decision making, steering patients away from valid services or therapies and unfair, non-competitive service delivery. **Possible penalties for violating the AKS** include: fines of up to \$25,000, up to five years in jail, and exclusion from Medicare and Medicaid care program business.

The physician self-referral laws (Stark Laws) (See 42 U.S.C. § 1395nn) are a set of United States federal civil laws that prohibit physician self-referral, specifically a referral by a physician of a Medicare or Medicaid patient to an entity providing designated health services (DHS) if the physician (or his/her immediate family member) has a financial relationship with that entity. Although the financial penalties may be even greater than with the AKS, these are non-criminal charges. Penalties for violations of Stark Law include denial of payment for the DHS provided, refund of monies received by physicians and facilities for amounts collected, payment of civil penalties of up to \$15,000 for each service that a person "knows or should know" was provided in violation of the law, and three times the amount of improper payment the entity received from the Medicare program, exclusion from the Medicare program and/or state healthcare programs including Medicaid and payment of civil penalties for attempting to circumvent the law of up to \$100,000 for each circumvention scheme.

Please refer to Table 1 at the end of this article for a summary of the characteristics of AKS and Stark.

CMS maintains a list of designated health services by CPT® code. That list is updated annually and available at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html

As part of efforts to review and refine regulatory processes to reduce administrative burden, CMS issued a Request for Information (RFI) regarding Physician Self-Referral Laws (Stark) via a proposed rule in June 2018 and accepted comments through August. The Department of Health and Human Services Office of the Inspector General (HHS-OIG) also actively sought input via RFI in a separate proposed rule on whether AKS rules present barriers to coordinated or value-based care and how any such barriers might be addressed. That proposed rule was released in August 2018 and included a comment period that ran until October 2018. ASA submitted comments on the AKS RFI which can be viewed here.

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We can anticipate further rulemaking but at this point, it is difficult to predict when that might happen. However, ASA members and their practices will need to stay informed on any changes to either of these sets of rules.

TABLE 1:

	Antikickback Statute	Physician Self-Referral Laws (Stark Laws)
Penalty types	Criminal and civil	Civil only
Proof of intent	Requires proof of improper intent	Strict liability
		(no proof of intent required)
Jail time	Up to 5 years	N/A
Financial penalties	Fines up to \$25,000	\$15,000 and 3x the amount of
		improper payment and civil penalties
		of up to \$100,000 per circumvention
		scheme
Applies to: Patients	Applies to Medicare and any	Applies only to Designated Health
	Federal Healthcare Program	Services (DHS) paid for by Medicare
Applies to: Healthcare providers	Applies to any referral source (not just physicians)	Must involve a physician and an entity
Exceptions	Yes, statutory exceptions and safe harbors available	Yes, exceptions available